

### **REMARKS**

Claims 1, 8, 9, 11, 12 and 14-23 are pending and stand ready for further action on the merits. Claims 2-7, 10 and 13 have been cancelled. Claim 11 has been withdrawn from consideration as being drawn to nonelected subject matter. The claims have been amended for clarity. Claim 1 has also been amended to recite that the 3<sup>rd</sup> stage distillation is carried out on the *distillate* from the 2<sup>nd</sup> stage distillation. Support for this amendment can be found in Fig. 1.

No new matter has been added by way of the above-amendment.

### ***Claim Objections***

The Examiner has objected to the claims because of informalities. Applicants believe that the above-amendment fully addresses the Examiner's objections. Reconsideration and withdrawal of the objections are respectfully requested.

### ***Claim Rejections - 35 USC § 112***

Claims 1, 8, 9, 12 and 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse the rejection.

#### **"Crude palm oil":**

The Examiner has objected to the phrase "crude palm oil" in claims 1 and 12. The Examiner believes that the term "crude" is a relative term which renders the claim indefinite. In response, Applicants have amended the claims by deleting the term "crude."

Claim 8:

The Examiner objects to the phrase "and heated to a temperature of 65 °C to 85 °C and slowly cooled" because it is allegedly unclear as to what is being heated and what is being cooled. The Examiner also believes that it is unclear as to what "of ratio 25:1:1" means.

In response, Applicants have amended claim 8 to clarify what is being heated and what is being cooled. With respect to the ratio, the Examiner will note that, for instance, Example 4 includes 0.1mL methanol, 0.1mL hot distilled water and 2.5mL hexane. As such, it is clear that the ratio is meant to be "by volume." Applicants have amended claim 8 to clarify that the ratio is by volume.

Claim 9:

The Examiner objects to claim 9. Specifically, the Examiner objects to the fact that the amounts of the ingredients are not set forth in terms of either "by weight" or "by volume" amount of the total composition.

Applicants note that, for instance, Example 9 includes 3 mL methanol and 5 mL hexane. As such, it is clear that the ratio "5:3" of claim 9 is meant to be "by volume." Applicants have amended claim 9 to clarify that the ratio is by volume.

Claim 23:

Claim 23 depends from claim 1. The Examiner objects to claim 23 for not further limiting claim 1. Claim 23 recites that the palm oil is converted "directly" into palm oil methyl esters, and claim 1 recites step i wherein palm oil is converted into palm oil methyl esters. Applicants respectfully submit that step i of claim 1 simply recites that the palm oil is converted, i.e., claim 1 is open to including more than one reaction pathway for performing the conversion. As such, claim 23 which requires direct conversion, limits the number of reaction pathways of step i of claim 1 for performing the conversion.

With respect to the remaining objections by the Examiner, Applicants respectfully submit that the present amendment addresses the Examiner's objections. Applicants respectfully submit that the claims, as currently amended, particularly point out and distinctly claim the subject

matter which Applicants regard as the invention. As such, reconsideration and withdrawal of the rejection are respectfully requested.

***Claim Rejections - 35 USC § 103***

Claims 1, 8, 9 and 12 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitsche (US Patent Number: 5,902,890), in view of Hunt (US Patent Number: 5,646,311) and Hirata (JP 09-176057 A). Applicants respectfully traverse the rejection.

The objective of the present invention is to make the palm oil based biodiesel (methyl esters) industry a viable industry at current high feedstock price. A step towards this end is that the inventive method minimizes the use of solvents in the purification steps by step-wise reducing the volume of sample.

Applicants respectfully submit that the inventive method is not taught or fairly suggested by the combination of Nitsche, Hunt and Hirata. Present claim 1 is as follows:

1. A method of extraction of phytosterols, squalene and vitamin E from the palm oil comprising the steps of:
  - a) conversion of the palm oil into palm oil methyl esters;
  - b) three stages of short path distillation of the palm oil methyl esters obtained in step a) to yield a phytonutrient concentrate;
  - c) saponification of the phytonutrient concentrate from step b) to give a saponified product;
  - d) crystallization of phytosterols;
  - e) solvent partitioning of vitamin E and squalene;

*wherein each of the three stages of short path distillation produces a distillate and a residue and wherein the third stage short path distillation is carried out on the distillate produced in the second stage short path distillation.*

With respect to step b), the Examiner is relying on Nitshche for teaching the three short path distillations to be carried out on the *residue*. However, Applicants have amended the process of claim 1 to clarify that the 3<sup>rd</sup> stage distillation is carried out on the *distillate produced in the second stage short path distillation.*

Accordingly, significant patentable distinctions exist between the present invention and the teachings of Nitshche.

In order to cure the deficiencies of Nitshche, the Examiner cites Hunt and Hirata. The Examiner appears to apply Hunt for teaching the crystallization of sterols and the Examiner appears to apply Hirata for teaching the removal of squalene and for teaching a specific solvent system.

In view of the fact that neither Hunt nor Hirata teach or suggest modifying the process of Nitshche to run a 3<sup>rd</sup> stage distillation on the *distillate produced in the second stage short path distillation*, Hunt and Hirata do not cure the deficiencies of Nitshche.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, there must be a reason why one of ordinary skill in the art would modify the reference or combine reference teachings to obtain the invention. A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Here, there is no rationale for the skilled artisan to modify the process of Nitshche to run a 3<sup>rd</sup> stage distillation on the *distillate produced in the second stage short path distillation*. As such, a *prima facie* case of obviousness cannot be said to exist. Reconsideration and withdrawal of the rejection are respectfully requested.

Application No. 10/642,596  
Amendment dated December 12, 2008  
Reply to Office Action dated September 12, 2008

Docket No.: 3587-0110P

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D., Esq. (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Dated: December 12, 2008

Respectfully submitted,

By

Paul C. Lewis

Registration No.: 43,368

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant